

**U.S. Department of Commerce
Patent and Trademark Office**

Serial No.
09/311,428

Applicants
John O'Connor et al.

Filing Date
May 13, 1999

**Group
1641**

INFORMATION DISCLOSURE CITATION
(Use several sheets if necessary)

[illegible][illegible]

OTHER DOCUMENTS (Including Author, Title, Date, Page)		
LVC	/	Bogart et al., (1989) "Human Chorionic Gonadotropin Levels in Pregnancies with Aneuploid Fetuses", <u>Prenat.Diagn.</u> 9: 379-384. (Exhibit 1);
LVC	/	Bogart et al., (1987) "Abnormal Maternal Serum Chorionic Gonadotropin Levels in Pregnancies with Fetal Chromosome Abnormalities", <u>Prenat.Diagn.</u> 7: 623-630. (Exhibit 2);
LVC	/	Cole et al., (1997) "Oligosaccharide Variants of hCG-related Molecules: Potential Screening Markers for Down Syndrome", <u>Prenat.Diagn.</u> 17: 1188-1190. (Exhibit 3);
LVC	/	Cole et al., (1998) "Hyperglycosylated hCG, A Potential Alternative To hCG in Down Syndrome Screening", <u>Prenat.Diagn.</u> 18: 926-933. (Exhibit 4);
EXAMINER <i>J.P. Cook</i>		DATE CONSIDERED <i>1/12/01</i>

***EXAMINER:** Initial if citation considered, whether or not citation is in conformance with MPEP 609: Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Applicant: John O'Connor, et al.
Serial No: 09/311,428
Filed: May 13, 1999

Exhibit A

NOV 13 2000

INFORMATION DISCLOSURE CITATION
(Use several sheets if necessary)

54205B/JPW/SHS/MVM

09/311,428

John O'Connor et al.

May 13, 1999

1641

[illegible][illegible]

LYC	✓	Spencer et al., (1993) "Stability of Intact Chorionic Gonadotropin (hCG) in Serum, Liquid Whole Blood, and Dried Whole-Blood Filter-Paper Spots: Impact on Screening for Down Syndrome by Measurement of Free β -hCG Subunit", <u>Clin.Chem.</u> 39: 1064-1068. (Exhibit 9);
		Spencer et al., (1997) "Biochemical Markers of Trisomy 21 in Amniotic Fluid", <u>Prenat.Diagn.</u> 17: 31-37. (Exhibit 10);
LYC	✓	Valerio et al., (1996) "Maternal Serum Screening of Fetal Chromosomal Abnormalities by AFP, UE3, hCG and free- β hCG", <u>Minerva.Ginecol.</u> 48: 169-173. (Exhibit 11);
		Wald et al., (1994) "Four-Marker Serum Screening For Down's Syndrome", <u>Prenat.Diagn.</u> 14: 707-716. (Exhibit 12);

ER Lisa. I Cook

DATE CONSIDERED

1/12/01

***EXAMINER:** Initial if citation considered, whether or not citation is in conformance with MPEP 609: Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

1449 NOV 13 2000 INFORMATION (Use sev...)

U.S. Department of Commerce
Patent and Trademark Office

Atty. Doc. No. [REDACTED]

54205B/JPW/SHS/MVM

Serial No.

09/311,428

Applicants

John O'Connor et al.

Filing Date

May 13, 1999

Group

1641

U.S. PATENT DOCUMENTS

[illegible]

FOREIGN PATENT DOCUMENTS

[illegible]

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

OTHER DOCUMENTS (Including <u>Ann. Med.</u>)	
W/C	✓ Wald et al., (1994) "First Trimester Biochemical Screening for Down's Syndrome", <u>Ann. Med.</u> 26: 23-29. (Exhibit 13) ;
W/C	✓ Zimmermann et al., (1996) "Age-Independent Indices in Second-Trimester Serum Screening for Down's Syndrome Are Useless", <u>Prenat. Diagn.</u> 16: 79-82. (Exhibit 14) .
W/C	Birken et al., (1993) "Separation of Nicked Human Chorionic Gonadotropin (hCG), Intact hCG, and hCG Beta Fragment From Standard Reference Preparations and Raw Urine Samples", <u>Endocrinology</u> 133: 1390-1397;
W/C	Birken et al., (1996) "Metabolism of hCG and hLH to Multiple Urinary Forms", <u>Mol. Cell Endocrinol.</u> 125: 121-131;

EXAMINER

DATE CONSIDERED

1/12/01

***EXAMINER:** Initial if citation considered, whether or not citation is in conformance with MPEP 609: Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Form PTO-1449

**U.S. Department of Commerce
Patent and Trademark Office**

Atty. Docket No.
54205B/JPW/SHS/MVM

Serial No.
09/311,428

INFORMATION DISCLOSURE CITATION

(Use several sheets if necessary)

Applicants
John O'Connor et al.

Filing Date
May 13, 1999

**Group
1641**

U.S. PATENT DOCUMENTS

[illegible]

FOREIGN PATENT DOCUMENTS

[illegible]

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

WC	Hoermann et al., (1994) "Immunological Recognition and Clinical Significance of Nicked Human Chorionic Gonadotropin in Testicular Cancer", <u>Clin.Chem.</u> 40: 2306-2312;
WC	Kovalevskaya et al., (1995) "HLH Beta Core Fragment Immunoreactivity in the Urine of Ovulating Women: A Sensitive and Specific Immunometric Assay for its Detection", <u>Endocrine</u> 3: 881-887;
WC	O'Connor et al., (1994) "Recent Advances in the Chemistry and Immunochemistry of Human Chorionic Gonadotropin: Impact on Clinical Measurements", <u>Endocr.Rev.</u> 15: 650-683;
WC	O'Connor et al., (1998) "Differential Urinary Gonadotropin Profiles in Early Pregnancy and Early Pregnancy Loss", <u>Prenat.Diagn.</u> 18: 1232-1240; (pages 1-9 Exhibit 10)

EXAMINER

DATE CONSIDERED

1/12/01

*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609: Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Form PTO-1449

U.S. Department of Commerce
Patent and Trademark Office

Atty. Do [REDACTED] No.

54205B/JPW/SHS/MVM 09/311,428

Serial No.

09/311,428

INFORMATION DISCLOSURE CITATION
(Use several sheets if necessary)

Applicants
John O'Connor et al.

Spiling Date
May 13, 1999

**Group
1641**

U.S. PATENT DOCUMENTS

[illegible]

FOREIGN PATENT DOCUMENTS

FOREIGN PATENT DOCUMENTS														
		Document Number							Date	Country	Class	Subclass	Translation	
		Yes	No											

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

OTHER DOCUMENTS	
WC	O'Connor et al., (1988) "Development of Highly Sensitive Immunoassays to Measure Human Chorionic Gonadotropin, its Beta-subunit, and Beta Core Fragment in the Urine: Application to Malignancies", <u>Cancer Res.</u> 48: 1361-1366;
WC	Wilcox et al., (1988) "Incidence of Early Loss of Pregnancy", <u>N.Engl.J.Med.</u> 319: 189-194;
WC	Zinaman et al., (1996) "Estimates of Human Fertility and Pregnancy Loss", <u>Fertil.Steril.</u> 65: 503-509;
WC	Acevedo et al., (1992) "Expression of Membrane-associated Human Chorionic Gonadotropin, Its Subunits, and Fragments by Cultured Human Cancer Cells", <u>Cancer</u> 69(7): 1829-1842;

EXAMINER

DATE CONSIDERED

1/12/01

*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609: Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Form PTO-1449

U.S. Department of Commerce
Patent and Trademark Office

Atty. Do [REDACTED] No.

54205B/JPW/SHS/MVM

Serial No.

09/311,428

INFORMATION DISCLOSURE CITATION
(Use several sheets if necessary)

(Use several sheets if necessary)

NOV 13 2000

Applicants

John O'Connor et al.

Filing Date

May 13, 1999

Group

1641

U.S. PATENT DOCUMENTS

[illegible]

FOREIGN PATENT DOCUMENTS

FOREIGN PATENT DOCUMENTS														
		Document Number						Date	Country	Class	Subclass	Translation		
												Yes	No	

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

WC	Berger et al., (1993) "Variants of Human Chorionic Gonadotropin from Pregnant Women and Tumor Patients Recognized by Monoclonal Antibodies", <u>J. Clin. Endocrinol. and Metabolism</u> 77(2): 347-351;
LWC	Birken et al., (1999) "Development and Characterization of Chorionic Gonadotropin in Serum and Urine from Patients with Trophoblastic Tumors", <u>Clinical Investigation</u> 71: 953-960;
LWC	Cole et al., (1991) "The Heterogeneity of Human Chorionic Gonadotropin (hCG). III. The Occurrence and Biological and Immunological Activities of Nicked hCG", <u>Endocrinology</u> 129(3): 1559-1567;
LWC	Hoermann et al., (1993) "Molecular Heterogeneity of Human Chorionic Gonadotropin in Serum and Urine from Patients with Trophoblastic Tumors", <u>Clinical Investigation</u> 71: 953-960;

EXAMINER

DATE CONSIDERED

1/12/01

*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609: Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

